

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC AND
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; and
TEVA PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 22-1461-CJB
ANDA CASE

Consolidated

**STIPULATION AND ORDER TO NARROW THE REMAINING ISSUES
BETWEEN PLAINTIFFS AND DEFENDANTS AUROBINDO
PHARMA LTD. AND AUROBINDO PHARMA USA, INC.**

This matter is before the Court on the joint motion of Plaintiffs Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc. (collectively “Amicus”) and Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo or “Defendants”) for entry of this Stipulation and Order.

WHEREAS, Amicus and Aurobindo jointly desire to narrow the remaining issues for resolution in this Action (as consolidated and as the parties have moved to consolidate, including with Civil Action Nos. 24-cv-01331-CFC, 24-cv-00698-CFC, and 22-cv-01467-CJB);

WHEREAS, Amicus owns U.S Patent No. 11,633,388 (the “388 Patent”), U.S. Patent No. 12,042,489 (the “489 Patent”), U.S. Patent No. 12,042,490 (the “490 Patent”), and U.S. Patent No. 11,833,164 (the “164 Patent”) (collectively, “the Infringed Patents”);

WHEREAS, Aurobindo submitted Abbreviated New Drug Application No. 217786 (“Aurobindo’s ANDA”) to the Food and Drug Administration under 21 U.S.C. § 355(j) seeking to

obtain approval to commercially manufacture and sell generic migalastat for treatment of Fabry disease;

WHEREAS, in this Action, Amicus alleges that Aurobindo infringed one or more claims of the Infringed Patents under 35 U.S.C. § 271(e)(2) by virtue of Aurobindo's submission of Aurobindo's ANDA to the Food and Drug Administration;

WHEREAS, Aurobindo agrees to stipulate to infringement of Claims 8 and 36 of the '388 Patent, Claims 17 and 23 of the '489 Patent, Claim 9 of the '490 Patent, and Claims 23, 24, 25, 26 and 27 of the '164 Patent (collectively, the "Asserted Claims");

WHEREAS, upon entry of this order, Amicus agrees to dismiss without prejudice its claims of infringement with respect to U.S. Patent No. 12,109,205 (the "'205 Patent") and Aurobindo agrees to dismiss without prejudice its claims of invalidity with respect to the '205 Patent;

WHEREAS, Amicus agrees to separately execute a covenant not to sue Aurobindo for infringement of the '205 Patent as to the Aurobindo ANDA product at issue in this Action;

WHEREAS, the entry of this order will cause the issues in this case to be narrowed to validity of the Asserted Claims.

IT IS HEREBY ORDERED, DECREED, and ADJUDGED as follows:

1. The Court has jurisdiction over Amicus and Aurobindo and the subject matter of this litigation.
2. Amicus owns and has standing to sue for infringement of the Infringed Patents.
3. The submission of Aurobindo's ANDA constitutes infringement of the Asserted Claims under 35 U.S.C. § 271(e)(2)(A), except as to any Asserted Claims that are later found invalid and/or unenforceable in a final non-appealable judgment.

4. Aurobindo will not contest in this Action that the commercial manufacture, use, sale, offer to sell, and/or importation of an Aurobindo Product prior to the expiration of the Infringed Patents would infringe the Asserted Claims, except as to any Asserted Claims of the Infringed Patents that are later found invalid and/or unenforceable in a final non-appealable judgment.

5. Nothing in this Stipulation and Order limits Aurobindo's rights under 35 U.S.C. § 271(e)(1) or Amicus's rights under 35 U.S.C. § 271(e)(4).

6. For avoidance of doubt, this stipulation does not affect Aurobindo's defenses and counterclaims of invalidity with respect to the Asserted Claims, and does not entitle Amicus to injunctive relief until those defenses and/or counterclaims are decided by the Court or withdrawn by Aurobindo. Except as expressly permitted by paragraphs 1 and 2 above, the parties agree that neither party shall use this Stipulation and Order as an admission or waiver of claims and/or defenses, in any manner, in this or any other forum, including but not limited to any other case, court, administrative agency, or administrative tribunal.

7. Each party is to bear its own costs, expenses, and attorneys' fees with respect to the aforementioned claims and counterclaims.

Dated: January 7, 2025

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IT IS SO ORDERED, DECREED, AND ADJUDGED this ____ day of _____,
2025.

The Honorable Christopher J. Burke
United States Magistrate Judge